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REMARKS

This is a full and timely response to the non-final Official Action mailed February 27, 2007. Reconsideration of the application in light of the above amendments and the following remarks is respectfully requested.

Claim Status:

Claims 16-23 have been withdrawn from consideration under the imposition of a previous Restriction Requirement.

By the present paper, various claims have been amended. For example, claim 1 is amended to correct a minor typographical error. This amendment to claim 1 does not, and is not intended to, narrow or change the scope of claim 1 in any degree. Other claims have been amended to broaden their scope.

No claims are cancelled or added by the present paper. Following entry of this amendment, claims 1-15 are currently pending for further action.

34 U.S.C. § 112:

The recent Office Action rejected claim 10 under 35 U.S.C. § 112, second paragraph, alleging two minor informalities relating to the preamble of claim 10. While the Applicant does not agree that claim 10 was not in compliance with § 112, to expedite the prosecution of this application, Applicant has amended the preamble of claim 10 in the present paper to address the issues raised in the Office Action. The amendments made in this regard do not, and are not

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intended to, narrow or change the scope of claim 10 in any degree. Following entry of this amendment, the rejection of claim 10 under 35 U.S.C. § 112 should be reconsidered and withdrawn.

Prior Art:

Claims 1-5, 7, 8 and 10-15 were rejected as anticipated under 35 U.S.C. § 102(b) by U.S. Patent No. 6,157,861 to Faltys et al. ("Faltys"). For at least the following reasons, this rejection is traversed.

Claim 1 recites:

In a neurostimulator implant system having multiple electrode contacts through which electrical stimuli are applied to tissue of a patient, and wherein an evoked compound action potential (ECAP) occurs in the tissue when an electrical stimulus of sufficient intensity has been applied to the tissue, and wherein the presence or absence of an ECAP in response to an applied stimulus serves as a useful objective indicator relative to the operation and functionality of the implant system, an improved method of eliciting an ECAP comprising the steps for:

generating electrical stimuli with selectable degrees of intensity;  
*delivering the electrical stimuli to at least two of the multiple electrode contacts, such that the at least two electrode contacts output an electrical current into the tissue, the electrode contacts being arranged such that the electrical current output by the at least two electrode contacts combines to provoke a single ECAP in the tissue and,*  
while delivering the electrical stimuli, gradually adjusting the intensity of the electrical stimuli and monitoring for the occurrence of said single ECAP with another separate electrode contact of the multiple electrode contacts;

noting the intensity of the applied electrical stimuli when the ECAP is first observed;

using the intensity of the electrical stimuli applied to the at least two electrode contacts that caused the ECAP to first occur as a guide to setting the intensity of the electrical stimuli of the neurostimulator implant system during operation of the neurostimulator implant system.

(Emphasis added).

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It should be noted that claim 1, as highlighted above, recites at least two electrode contacts that are used together to output an electrical current that combines to produce a single occurrence of an evoked compound action potential (ECAP).

In contrast, Faltys fails to teach or suggest the use of at least two electrode contacts used together to output an electrical current to produce a *single* ECAP. Moreover, the recent Office Action utterly fails to address this subject matter and does not indicate how or where Faltys teaches the method of claim 1 specifically including “delivering the electrical stimuli to at least two of the multiple electrode contacts, such that the at least two electrode contacts output an electrical current into the tissue, the electrode contacts being arranged such that the electrical current output by the at least two electrode contacts combines to provoke a single ECAP in the tissue.”

As stated in Applicant’s specification, “[t]raditional methods used to elicit the electrically-evoked compound action potential, or ECAP, deliver stimulation to a single electrode contact.” (Applicant’s specification, paragraph 0003). Faltys appears to be merely exemplary of this traditional state of the prior art described in Applicant’s specification.

While it has been the state of the art to use a single electrode to evoke a corresponding single ECAP, Applicant’s specification documents that “[t]here are cases where such application of a stimulus to a single electrode contact do[es] not evoke a suitable action potential.” (Applicant’s specification, paragraph 0003). Consequently, Applicant has discovered that two or more electrodes can be driven together, either simultaneously or in rapid succession, so as to output an electrical current that still only elicits a *single* ECAP, but does so more effectively and reliably than was possible with the prior art. According to Applicant’s specification, “electrical

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stimuli are applied simultaneously (or sequentially at a rapid rate) on selected small groups of electrodes while monitoring the ECAP on a nearby electrode. The presence of an observable ECAP advantageously validates operation of the implant device at a time when the patient may be unconscious or otherwise unable to provide subjective feedback.” (Applicant’s specification, paragraph 0024).

Despite the long and ongoing prosecution of this application, the Office has yet to cite any prior art that teaches or suggests the claimed method specifically including “delivering the electrical stimuli to at least two of the multiple electrode contacts, such that the at least two electrode contacts output an electrical current into the tissue, the electrode contacts being arranged such that the electrical current output by the at least two electrode contacts combines to provoke a single ECAP in the tissue.” With respect to the present Office Action, Faltys fails to teach or suggest the use of at least two electrode contacts used together to output an electrical current to produce an ECAP. Moreover, the recent Office Action utterly fails to address this subject matter and does not attempt to indicate how or where Faltys teaches this claimed use of at least two electrode contacts to produce a single ECAP. The Office Action does not even specifically allege that Faltys teaches this subject matter.

“A claim is anticipated [under 35 U.S.C. § 102] only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” *Verdegaal Bros. v. Union Oil Co. of California*, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987) (emphasis added). See M.P.E.P. § 2131. For at least these reasons, the rejection based on Faltys of claim 1 and its dependent claims should be reconsidered and withdrawn.

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Independent claim 10 similarly recites:

In a neurostimulator implant system having multiple spaced-apart electrode contacts for delivering electrical stimuli for stimulating tissue of a patient, said neurostimulator implant system being configured to elicit an evoked compound action potential (ECAP) from the tissue of the patient when an electrical stimulus of sufficient intensity is applied to the tissue, said system comprising:

means for generating electrical stimuli with selectable degrees of intensity;

*means for delivering the electrical stimuli to at least two of the multiple electrode contacts, such that the at least two electrode contacts output an electrical current into the tissue, while gradually adjusting the intensity of the electrical stimuli, the electrode contacts being arranged such that the electrical current output by the at least two electrode contacts combines to provoke a single ECAP in the tissue;*

means for monitoring another separate electrode contact of the multiple electrode contacts for the occurrence of said single ECAP, said separate electrode contact that is monitored being located near the at least two multiple electrode contacts to which the electrical stimuli is delivered;

means for noting the intensity of the applied electrical stimuli when the ECAP is first observed; and

means for using the intensity of the electrical stimuli applied to the at least two electrode contacts that caused the ECAP to first occur as a guide to setting the intensity of the electrical stimuli of the neurostimulator implant system during operation of the neurostimulator implant system.

(Emphasis added).

In contrast, as demonstrated above, Faltys fails to teach or suggest the claimed system including “means for delivering the electrical stimuli to at least two of the multiple electrode contacts, such that the at least two electrode contacts output an electrical current into the tissue... the electrode contacts being arranged such that the electrical current output by the at least two electrode contacts combines to provoke a single ECAP in the tissue.” “A claim is anticipated [under 35 U.S.C. § 102] only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” *Verdegaal Bros. v. Union Oil Co. of California*, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987) (emphasis added). See M.P.E.P. §

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2131. For at least these reasons, the rejection based on Faltys of claim 10 and its dependent claims should be reconsidered and withdrawn.

Additionally, various dependent claims of the application recite subject matter that is further patentable over the cited prior art. Specific, non-exclusive examples follow.

Claim 2 recites "wherein the step for delivering the electrical stimuli to at least two of the multiple electrode contacts comprises delivering the electrical stimuli to at least two adjacent electrode contacts of the multiple electrode contacts." Claim 11 recites similar subject matter. In contrast, however, Faltys does not appear to teach or suggest this subject matter, nor does the recent Office Action indicate how or where Faltys teaches this subject matter.

Claim 4 recites "wherein the step for delivering the electrical stimuli to at least two adjacent electrode contacts of the multiple electrode contacts comprises simultaneously delivering the electrical stimuli to at least two adjacent electrode contacts of the multiple electrode contacts." Claim 12 recites similar subject matter. In contrast, however, Faltys does not appear to teach or suggest this subject matter, nor does the recent Office Action indicate how or where Faltys teaches this subject matter.

Claim 5 recites;

wherein the at least two electrode contacts to which the electrical stimuli is delivered comprises a first group of electrodes, and wherein the method further includes; continuing to deliver electrical stimuli of varying intensities to select different groups of at least two adjacent electrode contacts while monitoring at least one electrode contact near the electrode contacts of the selected group for the occurrence of an ECAP;

noting the intensity of the applied electrical stimuli when the ECAP is first observed on the at least one electrode contact near the electrode contacts of the selected group;

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forming a contour of intensity levels associated with all of the selected electrode groups of electrode contacts at which the ECAP is first observed; and using the contour of intensity levels thus formed to define stimulation parameters thereafter used by the neurostimulation implant system to control the intensity of the electrical stimuli applied through the electrode contacts.

Claim 13 recites similar subject matter. In contrast, however, Faltys does not appear to teach or suggest this subject matter, nor does the recent Office Action indicate how or where Faltys teaches this subject matter.

Claim 7 recites "sequentially delivering the electrical stimuli to at least two adjacent electrode contacts of the multiple electrode contacts at a fast rate such that one occurrence of an ECAP is evoked." Claim 14 recites similar subject matter. In contrast, however, Faltys does not appear to teach or suggest this subject matter, nor does the recent Office Action indicate how or where Faltys teaches this subject matter.

For at least these additional reasons, the rejection of these and similar dependent claims should be reconsidered and withdrawn.

Claims 6 and 9 were rejected as being unpatentable under 35 U.S.C. § 103(a) over the combined teachings of Faltys and U.S. Patent No. 6,249,704 to Maltan et al. ("Maltan"). This rejection is respectfully traversed for at least the same reasons given above with respect to claim 1.

Additionally, claim 6 recites "wherein each group of electrodes to which the electrical stimuli are delivered comprises at least four adjacent electrode contacts." Claim 9 recites similar subject matter.

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The recent Office Action argues that "Faltys discloses the claimed invention as discussed in detail above except for explicitly stating that there are four electrodes or more in the array. Maltan discloses [an] electrode array with four or more electrodes." (Action of 2/27/07, p. 5). However, claims 6 and 9 do not merely recite an electrode area with four or more electrodes, as the Action implies. Rather, claims 6 and 9 recite that a group of at least four adjacent electrode contacts in an array are used together to provoke a single ECAP in patient tissue. Consequently, the Office Action fails to actually address the subject matter recited in claims 6 and 9.

As demonstrated above, the cited prior art of Faltys fails to teach or suggest using multiple electrode contacts to provide a single ECAP. Maltan similarly does not teach or suggest this subject matter and thus cannot remedy the clear deficiencies of Faltys in this regard. Consequently, the combined teachings of Faltys and Maltan are inadequate to support a rejection of claims 6 and 9.

"To establish prima facie obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974)." M.P.E.P. § 2143.03. Accord. M.P.E.P. § 706.02(j). For at least these additional reasons, the rejection of claims 6 and 9 should be reconsidered and withdrawn.

Double Patenting:

Lastly, the recent Office Action provisionally rejected claims 1-6 and 11-15 based on the judicially-created doctrine of obviousness-type double patenting in view of claims 1-6 of co-pending Application No. 10/698,098. Applicant notes that Application No. 10/698,098 has now issued as U.S. Patent No. 7,206,640 on April 17, 2007.



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Accordingly, Applicant has filed herewith a terminal disclaimer of the present application with respect to U.S. Patent No. 7,206,640. Therefore, the double patenting rejection may now be reconsidered and withdrawn.

Conclusion:

For the foregoing reasons, the present application is thought to be clearly in condition for allowance. Accordingly, favorable reconsideration of the application in light of these remarks is courteously solicited. If any fees are owed in connection with this paper that have not been elsewhere authorized, authorization is hereby given to charge those fees to Deposit Account 18-0013 in the name of Rader, Fishman & Grauer PLLC. If the Examiner has any comments or suggestions which could place this application in even better form, the Examiner is requested to telephone the undersigned attorney at the number listed below.

Respectfully submitted,

DATE: May 21, 2007



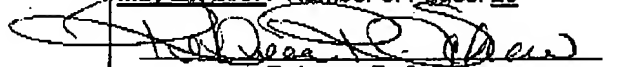
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Rebecca R. Schow